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Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Docketing and Service Branch

December 5, 1985

Gentlemen:

Relative to the proposed comprehensive revision to 10CFR35, following are my specific concerns on the July 26, 1985 draft. My concerns are minor in nature, and I believe the early implementation of this draft as a regulation would substantially benefit the practice of nuclear medicine.

Comments:

Section 35.30 ALARA program: The supplementary information raises the question as to whether all licensees should have a formal ALARA program. I believe the answer to that question should be "yes", and that small licensees should engage an outside observer to conduct the annual audit.

Section 35.35 Mobile Nuclear Medicine Service: The supplementary information, final paragraph, is confusing. I believe the intent of this regulation is to avoid the ambiguity of dual licensing coverage for a mobile service operating under its license in a nuclear medicine department which is itself licensed, not to prevent the mobile service from performing necessary services (additional equipment, overload relief) in a licensed department under that existing license. The current wording appears to prohibit any service, regardless of license coverage arrangements.

Section 35.37 Misadministrations: In the supplementary information section, opinions are solicited on the adequacy of the current misadministration Records and Reports requirements. In my opinion, the current system applies an appropriate balance to reports vs. patient protection. Based on substantial experience with this system for the 20 plus hospitals I am associated with, I feel that with the present records and reporting procedure the appropriate decisions are generally being made on notification of the patient, the reports are being forwarded to regulatory agencies as required, and the issue is being regarded seriously by the nuclear medicine personnel. The present system has resulted in substantial improvements in radiopharmaceutical control in error-prone departments with which I am familiar. I would suggest that the present system be retained.

DS10
add: Nathan L. McElroy, 39655
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Acknowledged by card DEC 23 1985 pd

Section 35.50 Dose Calibrators: ANSI N42.13-1978 has been updated and revised to N42.13-1985. The revised edition involved substantial input from NRC licensing personnel and more accurately reflects the requirements of this proposed part 35 revision.

Section 35.204 Moly breakthru: Exemption of the purchaser of prepared ^{99m}Tc from measuring moly breakthru has resulted in the unnecessary administration of ^{99}Mo to patients due to errors on the part of the supplier. Since this measurement is relatively easy, the regulations should at least encourage if not require this additional check.

Section 35.220 requires the possession of an ionization chamber for certain licensees. Since the dose measurement capability is generally stipulated as 2000 mrem/hr, and since there are G-M and proportional-type instruments on the market that are capable of measuring this dose rate and that are more easily maintained and have been acceptable to NRC licensing to date, this requirement should be less specific and more performance-oriented. This comment also applies to Sections 35.320, 35.420, 35.520 and 35.620.

Section 35.59 of the proposed regulations adequately covers all necessary requirements for use of brachytherapy sources except the necessary measurement of source strength, particularly for short-lived new sources. In my experience, the most likely problem with such sources is improper calibration of new, relatively short-lived sources.

Section 35.900 Radiation Safety Officer: The clear statement of requirements for radiation safety officer is most helpful and complete. I suggest that the NRC, in implementing this, also adopt the present custom of preceptor statements as utilized for medical users. Such verification by an RSO preceptor as defined under (b)(6) will help to avoid the falsification of prior experience that I have observed repeatedly in the past.

Yours truly,

Frank Massé

Frank Massé,
Certified Health Physicist